

**K946376 MAXX**Sep 22, 1995  
282 days to decisionK946376 · Product code: **HIS** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k946376/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Condom (HIS)
Date received	Dec 14, 1994
Decision date	Sep 22, 1995
Days to decision	282 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Mayer Laboratories</b>
Location	Oakland, CA, US
Contact	DABID MAYER
510(k) history	16 submissions · 16 cleared · 1987-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k946376/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 20, 2026